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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,915	11/28/2000	Naoki Nakayama	99,569-A	8656

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MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/02/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,915	Applicant(s) NAKAYAMA ET AL.	
	Examiner David Romeo ~~Elizabeth C. Kemmerer~~, Ph.D.	Art Unit ~~1646~~ 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10, 11 and 45, drawn to nucleic acids, vectors and host cells comprising same, and methods of recombinantly producing the encoded polypeptide, classified in class 536, subclass 23.1, for example.

II. Claims 9, 13-17, 37-42, 46 and 47, drawn to polypeptides and compositions comprising same, classified in class 514, subclass 2, for example.

III. Claims 12, 52 and 53, drawn to methods of screening for compounds that bind or inhibit a polypeptide, classified in class 436, subclass 501, for example.

IV. Claims 18-32 and 34-36, drawn to selective binding agents and methods of use, classified in class 530, subclass 387.1, for example.

V. Claim 33, drawn to method of administering a selective binding agent therapeutically, classification dependent upon structure of agent.

VI. Claims 43, 44 and 54, drawn to gene therapy compositions and methods, classified in class 514, subclass 44, for example.

VII. Claims 48 and 49, drawn to method of administering polypeptide therapeutically, classified in class 514, subclass 2, for example.

VIII. Claim 50, drawn to method of diagnosis, classification dependent upon whether protein or nucleic acid is measured.

IX. Claim 51, drawn to device comprising cells encapsulated within a membrane, classified in class 435, subclass 325, for example.

X. Claims 55 and 56, drawn to transgenic animals and methods of use, classified in class 800, subclass 8, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Invention I can be used to make protein recombinantly in vitro, or in hybridization analysis.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Invention I can be used to make protein recombinantly in vitro, or in gene therapy.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used therapeutically or to isolate receptors.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used to raise antibodies or to isolate receptors.

Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention II can be used therapeutically or to isolate receptors.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agents of

Invention IV can be used to label polypeptide in situ or isolate polypeptides form a sample.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of Invention III can be used to identify non-selective inhibiting agents.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I, II, IV, VI, IX and X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the binding agents of Group IV, such as in therapeutic or diagnostic methods (e.g., in screening). Although the binding agents of Group IV can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various

diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The DNA of Group I is independent and distinct from the gene therapy compositions of Group VI, because the DNA can be used in compositions appropriate for probes in hybridization analysis, or in compositions appropriate for expressing protein in vitro. The DNA of Group I is independent and distinct from the device of Invention IX, because the search for the device requires a membrane surrounding a population of cells, which is not required for the search of Group I. The DNA of Group I is independent and distinct from the transgenic animals of Group X, because the DNA can be used in materially different processes from a process of making the animal, such as in hybridization analysis or to make protein recombinantly in vitro. The protein of Group II is independent and distinct from the gene therapy compositions of Group VI, the device of Group IX and the transgenic animals of Group X, because the protein is not required for the manufacture of the gene therapy compositions, device or transgenic animals. Similarly, the binding agents of Group IV is independent and distinct from the gene therapy compositions of Group VI, the device of Group IX and the transgenic animals of Group X, because the binding agents are not required for the manufacture of the gene therapy compositions, device or transgenic animals. The gene therapy compositions of Group VI are independent and distinct from the device of Group IX and the transgenic animals of Group X, because the binding agents are not required for the manufacture of the device or transgenic animals. Finally, the device of Group IX is independent and distinct from the transgenic animals of Group X, because the device is not required for the manufacture of the animals.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups III, V, VII and VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search and consideration of agents that bind or inhibit proteins, which is not required by any of the other groups. Invention V requires consideration of agents that bind proteins and have a therapeutic benefit, which is not required by any of the other groups. Invention VII requires consideration of the therapeutic effects of polypeptides, which is not required by any of the other groups. Invention VIII requires consideration of disease diagnosis, which is not required by any of the other Groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of function. Specifically, each method of the remaining Invention pairs does not require the product of the remaining Invention pairs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. The Inventions as they pertain to the polypeptide of SEQ ID NO: 2 (or nucleic acids encoding same).

B. The Inventions as they pertain to the polypeptide of SEQ ID NO: 5 (or nucleic acids encoding same).

C. The Inventions as they pertain to the polypeptide of SEQ ID NO: 8 (or nucleic acids encoding same).

D. The Inventions as they pertain to the polypeptide of SEQ ID NO: 12 (or nucleic acids encoding same).

The inventions are distinct, each from the other because of the following reasons: Each sequence requires its own search of the literature and sequence databases. Search and examination of the Inventions as they pertain to all four sequences in one patent application would therefore present the examiner with an undue search burden.

Applicant is advised that the restriction between the four sequences is not a requirement for election of species, but is rather a further requirement for restriction among independent and distinct inventions. In order to be responsive, Applicant must elect one from I-X and one from A-D.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Romeo, Ph.D., whose telephone number is (703) 305-4050.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK
July 1, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER